REMARKS

Claims 1-111 were examined in the above-identified application. Claims 43-53 and 99-111 are canceled. Claims 1-42 and 54-98 are amended. New dependent claims 112-123 are added. Support for these amendments is identified in the following remarks. No new matter has been added by these amendments. Examination and reconsideration of all pending claims are respectfully requested.

Examiner Interview

Applicants (Craig Wong, Robert Whirley, and Bill Revelos) thank the Examiner for the kind and courteous telephone interview on January 24, 2005. Applicants discussed independent claim 1 with the Examiner. While no agreement was reached, Applicants believe the claims, as amended, are allowable over the cited references.

Supplemental Information Disclosure Statement

Applicants submit herewith a Supplemental Information Disclosure Statement. Applicant respectfully requests that the Examiner expressly consider and initial the references of and that the references appear among the references cited on any patent that issues.

Voluntary Amendments

Applicants have voluntarily amended the preambles of dependent claims 2-25, 17-30, 32-42, 71-85, and 87-98. Applicants do not believe that such amendments narrow or otherwise affect the scope of the claims.

Applicants have further amended claims 2-13, 15, 17-28, 30, 32-40, 42, 56-67, 69, 72-83, 85, 88-96, and 98 to change "where" to "wherein." Applicants do not believe that such amendments narrow or otherwise affect the scope of the claims.

Applicants have also made other voluntary minor amendments to claims 1, 6, 7, 14, 16, 21, 22, 29, 31, 34, 35, 41, 54, 55, 59, 60, 62, 68-71, 75-80, 84-87, 89-93, and 97-98.

No new matter has been added by any of the above amendments.

Claim Rejections under 35 U.S.C. §112

Claims 31, 41, and 52 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. While Applicants do not agree or acquiesce to such a rejection, Applicants have amended claims 31, 32, and 41 to more clearly claim the present invention.

The Examiner further rejected the claims which include trademark/tradenames TRUEGRID, MIMICS, DYNA3D, NIKE3D and GRIZ. Applicants note that per MPEP 608.01(v) trademarks are permissible in patent applications if the "product to which the trademark refers is set forth in such language that its identity is clear." Applicants submit that the specification clearly identifies the claimed product and provides a clear and definite meaning to the claim terms. *See* FIGS. 5A-8L and page 11, line 8 to page 32, line 18 for a description of TRUEGRID, MIMICS, DYNA3D, NIKE3D and GRIZ.

Independent Claim 43 and Claim 99

While Applicants do not agree or acquiesce to the Examiner's rejection, to simplify the issues and to expedite prosecution of the present application, Applicants have canceled independent claims 43 and 99 (and dependent claims 44-53 and 100-111). Applicants reserve the right to pursue the subject matter of such canceled claims in a continuation or continuation-in-part application.

Claims 61, 77, and 85-88

Applicants note that claims 61, 77, and 85-88 are pending in the present application and have not been objected to or rejected by the Examiner. Applicants respectfully request the Examiner to inform Applicants of the status of said claims in the next communication.

Claim Rejections under 35 U.S.C. §102

Claims 1-3, 8, 14, 16-18, 23, 29, 31, 32, 41, 43, 52, 54-56, 68, 70-72, 84, 97, 99, 100 and 110 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Berchem et al. (U.S. Patent 5,150,304). Such rejections are traversed in part and overcome in part as follows.

Amended independent claim 1 is directed toward a system for analyzing a medical device. The system comprises a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature. A mesh generator receives the geometric model of said anatomical feature and the geometric model of a medical device and generates a finite element model or mesh incorporating both said anatomical feature and said medical device. A stress/strain/deformation analyzer receives said mesh incorporating both said anatomical feature and said medical device, materials properties of said anatomical feature and said medical device, and load on said anatomical feature and/or said medical device, and simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.

As described on pages 3 to 6 of Applicants originally filed application, the systems of the present invention allow medical device designers to virtually test a proposed design of a medical device in a short period of time in a computer model of an actual anatomical feature or an idealized anatomical feature. Furthermore, the systems of the present invention allow the medical device designer the flexibility to vary material properties and configuration properties of the anatomical feature and/or the medical device, if desired. Variations of the

properties of the anatomical features may be used to simulate a large scale clinical trial for a given medical device, while variations of the properties of the medical device will allow the designer to determine optimum safety and efficacy of the medical device. Such a system is not described or suggested by Berchem et al.

Berchem et al. is directed toward a system and method of constructing an implantable joint prosthesis shaft based on a measured size of a cavity of a bone. While Berchem et al. ascertains a geometry of a bone cavity and determines a line of a geometrical centroid axis (Berchem et al. at col. 2, lines 30-34 and col. 4, lines 47-51), Berchem et al. merely describes using finite element analysis to develop a shaft core region of the joint prosthesis along the axis of the bone cavity (*see* Berchem et al. at col. 2, lines 35-38). Berchem et al. does not generate a finite element model or mesh of the anatomical feature, as is required by claim 1.

Berchem et al. also fails to provide the stress/strain/deformation analyzer provided in independent claim 1. While Berchem et al. describe a desire to provide a uniform distribution of the stress over the joint prosthesis (*see* col. 2, lines 40-42, col. 1, lines 65-68, col. 2, lines 1-2), such a vague description is insufficient to meet the limitations of claim 1. The stress/strain/deformation analyzer of claim 1 receives the finite element model or mesh of the anatomical feature and the medical device, material properties of the anatomical feature and the medical device, load on the anatomical features and/or the medical device, and simulates stresses, strains, and deformations of the medical devices. Applicants fail to see where Berchem et al. provides such a stress/strain/deformation analyzer.

In rejecting the stress/strain/deformation analyzer of claim 1, the Examiner further referenced col. 2, lines 59-68, and col. 3, lines 1-15 of Berchem et al. However, none of the referenced portions of Berchem et al. provide a stress/strain/deformation analyzer that incorporates the finite element model or mesh of both the anatomical feature and the medical device. Nor do the referenced portions of Berchem et al. describe a stress/strain/deformation analyzer that receives the material properties of the anatomical feature and the medical device,

and simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of the medical device.

Because there is no description or suggestion in Berchem et al. of the claimed mesh generator or the stress/strain/deformation analyzer, independent claims 1 is allowable. If the Examiner maintains the rejection of claim 1 over Berchem et al., Applicants request that the Examiner explicitly show where Berchem et al. describes every element of independent claim 1.

Applicants have made similar claim amendments to independent claims 16, 31, 54, 70, and 86. For at least the same reasons recited above in relation to independent claim 1, such independent claims and their dependent claims should also be allowable.

Dependent Claims

In addition to relying on allowable independent claims, the dependent claims further provide novel aspects that are not described or suggested by Berchem et al.. For example, dependent claims 2, 17, and 32 recite that the geometric model of the anatomical feature is an idealized geometric model. In rejecting these claims, the Examiner referenced Fig. 6, element 39 and col. 4, line 58 of Berchem et al.. Applicants have reviewed the referenced portion of Berchem et al. and element 39 in Fig. 6 is described as being a "prosthesis shaft." Such a prosthesis shaft is not an idealized geometric model of an anatomical feature. For such reasons, dependent claims 2, 17, and 32 are allowable over Berchem et al..

Dependent claims 14, 29, 41, 52, 68, 84,97 and 110 generally provide a "visualization tool" that displays one or more of the stresses, strains, and deformations of the medical device. In rejecting these claims, the Examiner referenced col. 4, lines 52-63 of Berchem et al.. Applicants have reviewed the referenced portions of Berchem et al. and fail to see any description of displaying stress, strain or deformations of the medical device. The referenced portion appears to only provide prosthesis model 36, and there is no description or suggestion that the prosthesis model output provides any visual representation of stress, strain, or deformation. Consequently, dependent claims 14, 29, 41, 52, 68, 84,97 and 110 should be allowable over Berchem et al..

In rejecting claims 8, 23, 61 and 77 the Examiner stated "Berchem et al. discloses a system where said geometry generator is MIMICS." In the next sentence the Examiner then states that "Berchem does not specify that the geometry generator is MIMICS because that is not the preferred embodiment...." (emphasis added) The Examiner then concluded that "it is well known in the art to use MIMICS...." Applicants response is in two parts:

First, it is well established that in order to anticipate a claim every element must be shown in the reference. Since the Examiner has not shown where Berchem et al. describes that the geometry generator is MIMICS, dependent claim 8, 23, 61, and 77 are not anticipated by Berchem et al. Second, the Examiner has provided no evidence to support the statement that it is well known in the art to use MIMICS...." If the Examiner is to continue to reject the claims over Berchem et al., Applicants respectfully request that the Examiner provide documentary evidence to support the statement that "it is well known in the art to use MIMICS..."

Claim Rejections under 35 U.S.C. §103(a)

Claims 5-7, 20-22, 33-35, 44-46, 58-60, 74-76, 90 and 101-103 are rejected as allegedly being unpatentable over Berchem et al. in view of Leotta et al. Such rejections are traversed as follows.

In rejecting the claims, the Examiner recognized that Berchem et al. discusses applications for bones. Specifically, the Examiner stated:

> Although the Berchem et al. reference primarily discusses applications for bones that is just a preferred embodiment of Berchem et al. it is known in the art to design an endovascular prosthesis utilizing the same/steps/equipment disclosed by Berchem et al. (page 6 of office action)

Applicants response is in three parts. First, Applicants disagree with the Examiner's unsupported statement that "it is known in the art to design an endovascular prosthesis utilizing the same steps/equipment disclosed by Berchem et al." Applicants

respectfully request that the Examiner provide some documentary evidence that supports the Examiner's statement.

Second, there is nothing in Berchem et al. that suggests that the invention is directed toward anything beyond an implantable joint prosthesis that is for placement in a bone cavity of a bone.

Finally, a person of ordinary skill in the art reading Berchem et al. would not be motivated to combine Berchem et al. with Leotta et al. Specifically, the Leotta et al. reference merely describes a method of using ultrasound for measuring progressive changes in a vein graft geometry (Abstract), while Berchem et al. is directed at methods of constructing an implantable prosthesis (*See* Berchem et al. "Object of Invention"). A person of ordinary skill in the art would not have any motivation to combine a reference that measures change in a graft geometry with a reference that is directed toward constructing a joint prosthesis for a bone cavity.

For the above reasons, dependent claims 5-7, 20-22, 33-35, 44-46, 58-60, 74-76, 90 and 101-103 are allowable over the cited references.

Claims 4, 19, 57 and 73 are rejected as allegedly being unpatentable over Berchem et al. in view of Reisfeld (U.S. Patent No. 6,301,496). Claims 9, 24, 36, 47, 62, 78, 91, and 104 are rejected as allegedly being unpatentable over Berchem et al. in view of Bossart et al. Claims 10, 11, 15, 25, 26, 30, 78, 38, 42, 48, 49, 53, 63, 64, 67, 69, 79, 80, 83, 89, 92, 93, 96, 98, 105, 106, and 111 are rejected as allegedly being unpatentable over Berchem et al. in view of Dovey et al. Claims 12, 13, 27, 28, 39, 40, 50, 51, 65, 66, 81, 82, 94, 95, 107, and 108 are rejected as allegedly being unpatentable over Berchem et al. in view of Dovey et al. and further in view of Holzapfel et al. Such dependent claims should be allowable at least for depending from an allowable independent claim.

Added Claims

Applicants have added new dependent claims 112-123. Such new dependent claims depend from allowable independent claims and should be allowable for at least that reason.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: February 1, 2005

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